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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,982	10/27/2000	F. Richard Bringhurst	0609.4430001/JAG/CMB	1728

26111 7590 08/30/2004

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EXAMINER

ULM, JOHN D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/696,982

**Applicant(s)**

BRINGHURST ET AL.

**Examiner**

John D. Ulm

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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1) Claims 24 to 35 are pending in the instant application. Claims 9 to 23 have been canceled and claims 24 to 35 have been added as requested by Applicant in the correspondence filed 21 June of 2004.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) Claims 24 to 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. These claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "said second cell line also has inhibited  $G_s$  signaling of u-PA activity" has no basis in the instant application as filed. This language was not present in the application as filed and constitutes a new inventive concept because it does not inherently flow from the original disclosure.

The text on page 17 of the instant specification described the two cell lines employed in the majority of experiments disclosed therein. Those cell lines were described on page 17 of the specification as "two representative cell lines, HKRK B7 and HKRK B28, which express 950,000 and 280,000 hPTHR per cell, respectively".

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There is no indication that either of those cell lines had "inhibited  $G_s$  signaling of u-PA activity".

The only other cell line employed in a comparative manner was described on page 25 of the instant specification as "AB45 cells" "in which human PTHRs (370,000/cell) were co-expressed with REV AB, a dominant-negative inhibitor of both basal and hormone-stimulated protein kinase A (PKA)". The text on page 10 of the specification states that "in LLC-PK1 cells, both the PKA and PKC pathways are linked to U-PA production" and that " $G_s$  and  $G_q$  proteins activate the PKC pathway and thereby increase U-PA production in LLC-PK1 cells". Therefore, one would not conclude that AB45 cells had "inhibited  $G_s$  signaling of u-PA activity" since  $G_s$  activates the PKC pathway and it was the PKA pathway that was inhibited by the heterologous REV AB gene in those cells.

If Applicant can identify that portion of the instant specification, as filed, which serves as a basis for the limitation "said second cell line also has inhibited  $G_s$  signaling of u-PA activity" they are encouraged to do so in response to this action. Those portions of the specification that were identified by Applicant in the correspondence of 21 June of 2004 as providing support for the new claims have been carefully reviewed and they do not support the limitation "said second cell line also has inhibited  $G_s$  signaling of u-PA activity".

5) Claims 24 to 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are vague and indefinite

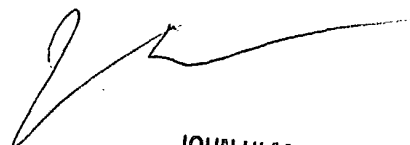
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because the limitation "has inhibited  $G_s$  signaling of u-PA activity" requires a point of reference, such as "relative to said first cell line", and none is given.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kunz Gary can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN ULM  
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